



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	9401.R0
True Name	Feline Interleukin-2 Immunomodulator, Live Canarypox Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 17, 2019

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety under field conditions
<b>Product Administration</b>	<p>Total of 6 doses. The 1<sup>st</sup> dose was administered approximately one week prior to surgical removal of the tumor. The rest of the doses were administered post surgery. The 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> doses were administered weekly, starting one week after surgery. The 6<sup>th</sup> dose was administered 2 weeks after the 5<sup>th</sup> dose.</p> <p>Each dose is divided into five equivalent aliquots. The injections are distributed around the tumor before surgery then at each corner of a 5 cm square field centered over the surgical scar plus one injection near the center of the scar.</p>
<b>Study Animals</b>	<p>15 cats</p> <ul style="list-style-type: none"> <li>• 6-18 years of age; 3 males/12 females</li> <li>• Diagnosed with histologically confirmed feline fibrosarcoma amenable to surgical excision of the tumor</li> </ul>
<b>Challenge Description</b>	Not applicable
<b>Interval observed after challenge</b>	<p>Cats were observed by the veterinarian for acute reactions after each administration and examined prior to the subsequent administration.</p> <p>Owners recorded observations daily until 2 weeks after final vaccination.</p>
<b>Results</b>	<p>Two cats were withdrawn from the study after administration of the 1<sup>st</sup> dose.</p> <p>Four cats were enrolled post-surgery and were administered all 6 doses after enrollment.</p> <p>One cat completed the vaccine series with tumor recurrence within 8 days after the final dose.</p> <p>Results are found in tables on following page.</p>
<b>USDA Approval Date</b>	December 26, 2013

**Table 1: Number of Treatments by site and treatment (injection) number**

Site	T1	T2	T3	T4	T5	T6	Total/Site
1	3	3	3	3	3	3	18
2	4	2	2	2	2	2	14
4	8	8	8	8	8	8*	48
Total/treatment	15	13	13	13	13	13	80

T is treatment (injection) number

\*One cat completed the treatment protocol but was euthanized prior to the final examination.

**Table 2: Incidence of Acute Post –Treatment Reactions. Cats may be counted in more than one clinical sign category.**

Clinical sign	Number of events in 80 treatments
Injection site stinging	19
Injection site bleeding	6
Injection site bruising	1
Vocalization	1

**Table 3: Summary of veterinarian reported events. Cats may be counted in more than one clinical sign category.**

Clinical sign	Number of events in 80 treatments
Depression	1
Dermal plaques at surgical incision	1
Diarrhea	1
Enlarged lymph node	1
Febrile	1
Injection site dermatitis	1
Injection site swelling	1
Seroma	1
Surgical site abscess	1

**Table 4 : Summary of owner observations. Cats may be counted in more than one clinical sign category and have multiple reports of the same sign after separate treatments. Events are reported only once per treatment, even if they were reported on multiple days. Events duplicated by veterinarian reports are found in Table 2.**

Clinical sign	Number of events in 80 treatments
Bruise	1
Decreased appetite	4
Depression	1
Diarrhea	4
Drainage	1
Enlarged lymph node	3
Hair loss	1
Hiding	1
Increased drinking	1
Lameness	1
Noted abnormal with no event reported	1
Painful to touch	4
Quiet	2
Redness at surgical site	2
Surgical site bruising	1
Swelling	2
Tiredness	1

**Table 5: Summary of owner observations by treatment number. Cats may be counted in more than one clinical sign category. The same cat may be counted multiple times for one treatment period and over multiple treatment periods.**

Treatment	T1	T2	T3	T4	T5	T6	Total
Number of Owners	15	13	13	13	13	13	80
Owners Reporting adverse events	7	3	5	2	4	1	22
Depression	0	0	0	0	1	0	1
Decreased appetite	1	0	1	3	1	0	6
Pain	5	2	1	0	1	0	9
Redness at surgical site	2	1	0	0	0	0	3
Swelling	3	0	0	0	0	0	3
Other as listed in table 4	15	2	9	1	5	3	35

T is treatment (injection) number